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EXAMINER
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ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/732,802	SERAFICA ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,19,26-31,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,19,26-31,33 and 34* is/are rejected.

7)☒ Claim(s) *34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11, 19, 26-31, and 33-34 are pending. Applicants previously cancelled claims 12-18 and 20-25. Applicants have newly cancelled claims 32 and 35. Applicants have amended claims 1, 3-4, 11, 19, and 33-34. Claims 36-38 are new. Receipt and consideration of Applicants' amended claim set and remarks/arguments submitted on 15 February 2008 are acknowledged. Applicants are advised that a different Examiner is examining the instant application. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments.

Drawings

The drawings are objected to because the legend of Figure 1 does not identify which data points correspond to donation per the description of Figure 1 in paragraph 27 of Applicants' specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet"

or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. **The objection to the drawings will not be held in abeyance**.

Claim Objections

Claim 34 is objected to because of the following informalities: (a) it appears that the word "in" at the beginning of claim 34 was inadvertently included and (b) the word "dressing" is misspelled as "dress" on line 2 of claim 34. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 26-31, 33 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the wound site" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 is vague and indefinite because it is unclear whether the expression contained within parentheses on line 2 of said claim is a required claim limitation, a description of the LAL test, or an example of a negative result. Appropriate correction and clarification are required.

Claim 36 is vague and indefinite, because it is unclear to what the microbial cellulose is exposed to at 30-100 °C for about 1-4 hours. Appropriate clarification and correction are required.

The remaining claims are rejected as depending from a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 9-11, 19, 26-31, 33-34, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ring et al. (U.S. Patent No. 4,588,400).

Applicant Claims

Applicants claim (1) a method of treating chronic wounds in humans comprising (a) providing a kit comprising a nonpyrogenic biocompatible microbial cellulose dressing and a moisture-proof package containing said dressing, (b) applying said nonpyrogenic biocompatible cellulose dressing to the wound site, wherein said microbial cellulose dressing consists essentially of water and from 1.5-4.5 wt. % of microbial cellulose, wherein the wound dressing is capable of donating greater than 75% of its liquid weight to a dry or necrotic portion of a chronic wound and absorbing liquid in an amount effective for treatment of a chronic wound; (2) a method for preparing a wound dressing comprising (a) statically producing microbial cellulose pellicle using Acetobacter xylinum, (b) isolating the pellicle with a cellulose to water ratio in the range of 1:100 to 1:500, and (c) drying said isolated pellicle to form a dressing as described in (1); and (3) a method for preparing a wound dressing comprising (a) providing a nonpyrogenic biocompatible microbial cellulose dressing as described in (1) and placing said dressing in a moisture-proof package, and in some embodiments further comprising providing instructions with said dressing.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Ring teaches liquid loaded pads for medical applications that is useful as wound and burn dressing and are prepared from pellicles of **microbially-produced cellulose** obtained, for example, from ***Acetobacter xylinum***, and wherein the liquid loaded pad may comprises a **weight ratio of liquid to cellulose from about 5:1 to 150:1**, wherein suitable liquids include distilled water, saline, glycerol, PEG, lower alcohols, and mixtures thereof (abstract; col. 3, lines 39-43; Examples 1-2 and 8 [col. 4, line through col. 5, line 43 and col. 6, lines 45-55]; claims 1-3). Ring teaches that when used as a wet dressing the liquid loaded pad may be combined with a backing layer and that **the dressing should provide a source of moisture over an extended period of time and ensure an antibacterial environment** (col. 9, lines 24-49). For example, Ring indicates that the wet dressing **loaded with an aqueous solution containing an antimicrobial agent may be applied to an ulcer (i.e. a chronic wound)** and covered with an occlusive film to prevent evaporation of moisture from the dressing. Ring teaches that an additional feature of the wet dressings of the invention is their ability **to absorb large quantities of fluid from a wound site**, when the dressing is applied in less than saturated conditions (col. 10, lines 33-43), wherein the dressing **can also be used to absorb wound exudate**. Ring's microbially produced cellulosic pellicles may be cut into any size, and thus any shape (col. 3, lines 50-52). The wound dressing or pad may have a cellulose to liquid ratio ranging from 1:5 to 1:150 (Ring claim 2), which overlaps with the cellulose to water ratio recited in Applicants' claim 19. Ring's claim 23 indicates that the liquid may be **water** and Ring's claim 24 explicitly teaches **a dressing that is pyrogen-free** (i.e. nonpyrogenic). The preparation of cellulose from ***Acetobacter xylinum*** is explicitly described in Example 1 (col. 4, line 46 through col. 5, line 27) including the steps of producing the microbial cellulose from ***Acetobacter xylinum***, isolating the

microbial cellulose pellicle, and sterilizing by autoclaving or radiation. Autoclaving involves heating, thus, this reads on drying the isolated microbial cellulose.

Ring also teaches that the invented microbial cellulose wound dressing/pads are packaged in a **sterile hermetically-sealed moisture proof containers** (col. 10, lines 56-64).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Ring does not anticipate the rejected claims, because Ring does not exemplify a method of treating chronic wounds or preparing a wound dressing with the same steps as recited in Applicants' claim 19. However, Rings' teachings are suggestive of a method of treating chronic wounds and making preparing a wound dressing.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been prima facie obvious per the teachings of Ring to provide a kit containing a nonpyrogenic biocompatible microbial cellulose dressing in a moisture-proof package and applying said dressing to a wound site, because Ring teaches wound dressings/pad comprising microbial cellulose that is pyrogen free and suggests that such a wound dressing/pad is stored in a hermetically-sealed moisture-proof container. Although Ring is silent as the frequency at which a wound dressing applied to a chronic wound is changed, it is the Examiner's position that an ordinary skilled artisan would routinely evaluate wound dressings on a regular basis and change said dressings as appropriate. Furthermore, the frequency of changing a wound dressing applied to a wound would be a result effective parameter that an ordinary skilled artisan would

optimize in the treatment of wounds. Regarding the amount of microbial cellulose, Ring teachings an overlapping range for the amount of water and microbial cellulose in the wound dressing. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Regarding the properties of donating moisture and absorbing liquid from a wound, Ring's microbial cellulose wound dressing are taught to exhibit these properties. Ring's wound dressings are taught as comprising an amount of microbial cellulose overlapping with that required by Applicants' claims, thus, Ring's wound dressings would necessarily exhibit substantially similar or same donation, absorption, negative LAL test, negative primary irritation test, and other improved properties relative to a non-adhesive gauze dressing, because these properties are a consequence of the wound dressing. Regarding the inclusion of instructions with a nonpyrogenic biocompatible microbial cellulose wound dressing, it is the Examiner's and the Office's position that the inclusion of instructions is not a patentably distinguishing feature or step. This position is also supported by case law (see *In re* Ngai, 70 USPQ2d 1862 (CA FC 2004)).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 19, 33, and 37-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,390,499 (USPN '499). Although the conflicting claims are not identical, they are not patentably distinct from each other because although the kit claims of USPN '499 do not recite a method of treating chronic wounds, the kits claimed in USPN "499 which comprise (i) a nonpyrogenic microbial cellulose wound dressing consisting essentially of water and from 1.5-4.3% microbial cellulose, (ii) a moisture proof package containing said wound dressing, and (iii) instructions for applying the microbial cellulose wound dressing to a chronic wound in a human patient suggest the method claimed in the instant application. Regarding the amount of microbial cellulose, the amounts recited in the claims of USPN '499 overlap with the amounts recited in the rejected claims of the instant application, and thus application of the wound dressing contained in the moisture proof kit claimed in USPN '499 would necessarily yield the same results and the wound dressing would exhibit the same properties. Regarding claim 19 of

the instant application, claim 10 of USPN '499 recites the same process steps, but does not recite the liquid donating or absorbing properties of the microbial cellulose produced. However, this is not a deficiency because the microbial cellulose contained in the kit of claim 10 of USPN '499 is the same as that made in the method of claim 19 of the instant application and would necessarily exhibit the same liquid donation and absorption properties. Claims 37-38 of the instant application, which claim a method of preparing a wound dressing, are rendered obvious by the kit claims of USPN '499, because the kits claimed in USPN '499 are necessarily produced by the method of claims 37-38 of the instant application. Regarding claims 6-8 of the instant application, the claims of USPN '499 do not specify that the chronic wound is a venous ulcer, pressure ulcer, or diabetic ulcer. Paragraph [0001] of USPN '499 identifies pressure sores, venous ulcers, and diabetic ulcers as examples of chronic wounds contemplated as being treatable with the microbial wound dressing contained in the claimed kits. It is proper to turn to a patent's or application's disclosure as a dictionary and/or to understand the scope of what is meant by a term in a claim and what constitutes and obvious modification. This position is supported by the courts. See *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-11, 19, 33, and 37-38 *prima facie* obvious over claims 1-11 of U.S. Patent No. 7,390,499 (USPN '499).

Claims 1-11, 19, 26-31, 33, and 36-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 18, and 25-28 of copending Application No. 10/173,576 (copending '576). Although the

conflicting claims are not identical, they are not patentably distinct from each other because both claim sets claim (1) methods of treating chronic wounds in a human by providing a kit comprising a nonpyrogenic biocompatible microbial cellulose dressing and a moisture-proof package containing said dressing, wherein the dressing of both claim sets has substantially overlapping amounts of microbial cellulose (i.e. from about 1.5% to about 4.5% in copending '576 vs. from 1.5% to 4.5% in the instant application); and (2) methods of preparing microbial cellulose using *Acetobacter xylinum* to isolate a pellicle having substantially overlapping cellulose to water ratios (i.e. a ratio of about 1:100 to about 1:500 in copending '576 and a ratio of 1:100 to 1:500 in the instant application). The method claimed in copending '576 necessarily yields the same results and the microbial cellulose dressing applied in the methods of copending '576 necessarily has the same properties, as are recited in claims 26-31 of the instant application, because the methods are essentially the same and use essentially the same nonpyrogenic biocompatible microbial cellulose wound dressing. Claims 37-38 of the instant application are rendered obvious by virtue of the fact that the method steps of claims 37-38 necessarily produce the kit provided for in the method claims of copending '576. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-11, 19, 26-31, 33, and 36-38 *prima facie* obvious over claims 1-10, 18, and 25-28 of copending Application No. 10/173,576 (copending '576).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4 and 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16-17, and 26-27 of copending Application No. 10/345,394 (copending '394). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim sets claim methods of treating chronic wounds by application of a nonpyrogenic, biocompatible, microbial-derived cellulose wound dressing. Claim 1 of the instant application has been described supra. Claim 16 of copending '394 claims a method of treating chronic wounds by application of nonpyrogenic, biocompatible, microbial-derived cellulose amorphous gel wound dressing comprising about 4% to 7% by weight of microbially produced cellulose, wherein the dressing is flowable. The primary difference between the claimed methods is that the claims of the instant application do not state whether the microbial cellulose wound dressing has an amorphous or non-amorphous form or that the wound dressing is flowable. However, because the microbial cellulose content of the wound dressing utilized in the claimed method of copending '394 overlaps with that utilized in the method of the instant application, both wound dressings necessarily must exhibit the same properties. This position is supported by dependent claim 26 of copending '394, which specifically recite that the wound dressing donates 40-85% of its liquid weight and absorbs 10-50% of its weight. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-4 and 9-11 *prima facie* obvious over claims 1, 16-17, and 26-27 of copending Application No. 10/345,394 (copending '394).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-11, 19, 26-31, and 33-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 35-40 of copending Application No. 10/425,978 (copending '978). Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets claim (1) methods of treating a chronic wound by applying a wound dressing comprising the same amount of microbial cellulose and (2) similar methods of making a wound dressing utilizing *Acetobacter xylinum* to isolate a microbial cellulose pellicle. The claims of the instant application have been described supra. Claim 35 of copending '978 claims a method of treating a chronic wound by applying a wound dressing consisting essentially of from 1.5 to 4.5% by wt. of microbial cellulose, water, and polyhexamethylene biguanide (PHMB, a known antimicrobial agent). Because the microbial cellulose content in the wound dressings applied in the claims of copending '978 and the instant application are the same, both wound dressings necessarily will exhibit the same liquid donation/absorption properties as well as other properties. The claims of the instant application do not recite PHMB. It is the Examiner's position that the presence of PHMB does not materially affect the liquid donation/absorption properties of the wound dressing, thus the inclusion of an antimicrobial agent does not render the claims of copending '978 unobvious vis-à-vis the claims of the instant application. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-11, 19, 26-31, and 33-34 *prima facie* obvious over claims 13 and 35-40 of copending Application No. 10/425,978 (copending '978).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-11, 19, 26-31, and 33-34 are rejected. Claim 34 and the drawings are objected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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